ATTACHMENT A

#31 Amp 4/28/03

I hereby certify that this correspondence is being sent by facsimile transmission in accordance with § 1.6(d) addressed to, Art Unit 1615, Before Final Facsimile No. (703) 872-9306, the Commissioner for Patents, Washington, D.C. 20231 on the date shown below.

Date: April 17, 2003 By: Carol A. See

Carol A. See

PATENT
Docket No. GC530-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Becker et al.	)	Group Art Unit: 1615
	)	
Serial No.: 09/285,632	)	Examiner: Susan Tran
	)	
Filed: April 2, 1999	)	
	)	
For: MODIFIED STARCH COATING	)	

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Mark S. Gebert, do hereby declare:

1. THAT, I have been an employee of Genencor International, Inc. since August 4, 1997.

2. THAT, I have received Bachelor of Science degrees in Chemical Engineering from The Massachusetts Institute of Technology in Cambridge, MA in 1986 and Doctor of Philosophy degrees in Chemical Engineering from Northwestern University in Evanston, IL in 1991 .

3. THAT, a copy of my Curriculum Vitae is attached hereto as Appendix A.

4. THAT, I am one of the inventors of the subject matter disclosed and claimed in the above-referenced application and I have reviewed and am familiar with the contents of U.S. Patent Application Serial No. 09/285,632, including currently pending claims. I also am familiar with the Oshlack et al. U.S. Pat nt No. 5,639,476, patent, which patent describes a delayed

release coating that includes in every embodiment a hydrophobic acrylic polymer which is insoluble.

5. THAT, I conducted the following experiment to demonstrate the fact that the coating claimed in the above-referenced application is readily soluble or dispersible to allow rapid release of an active ingredient. Specifically, dissolution of 127 mg. of granules having the enzyme protease and a coating of equal parts of Pure Cote (modified starch) and methyl cellulose were placed in one liter of distilled water and stirred at 200 rpms using a 1 inch stir bar at room temperature. 10 microliter aliquots were removed from the beaker at regular time intervals. The enzymatic activity of the aliquots was measured using a conventional kinetic based spectrophotometric assay. The presence of enzyme activity resulted in an increase in the slope of optical density versus time (OD/min) and demonstrated rapid release of the enzyme. The amount of enzyme released was calculated from the OD/min values. The table below shows the amount of enzyme released in milligram units, and release leveled off in approximately 1 to 6 minutes when substantially all of the enzyme was released. Subsequent timed samples showed no significant change in OD/min. The table demonstrates that the coating is highly soluble and allowed release of substantially all of the enzyme in less than 6 minutes, as opposed to the partial, and substantially delayed release of a relatively small amount of enzyme in Oshlack after, for instance 1 hour. Adding hydrophobic acrylic polymer would result in loss of the rapid release.

Time in Seconds	Enzyme Released (mg)
0	0.0
15	0.0
30	1.4
45	4.9
60	6.0
90	6.2
120	6.3
180	6.4
240	6.6
300	6.3
360	6.8
420	6.3
480	6.2

6mw

6. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: April 17, 2003 Signed: Mark S. Gebert

Mark S. Gebert